Manufacture of drugs under loan licence

2835. SHRIMATI MAIMOONA SULTAN: Will the Minister of INDUSTRY be pleased to state:

(a) whether it is a fact that Hoechst, Glaxo, Searle, Roche, Pfizer, Wockhardt Fairdeal Corporation, Warner Hindustan, Bayer had made arrangements for manufacture of formulations under Loan licence as well as marketing arrangements with certain companies;

(b) if so, names of the companies with whom arrangements had been made along with full details;

(c) whether it is a fact that Directors of some of these companies have blood relation with the directors of other companies and such arragements have been made to pass on the profits; if so, what are the details of the relations;

(d) whether these companies took such permissions from Government; and

(e) if so, when and what are the basis of such permissions and if not, what action was taken against these companies for contravention of rules, regulations and laws?

THE MINISTER OF STATE IN THE DEPARTMENT OF CHEMICALS AND PETROCHEMICALS (SHRI R. K. JAICHANDRA SINGH): (a) to (e) According to the 1978 Drug Policy, no FERA company will be given loan licence for operating in the drugs field. As of now, among the companies referred to in the question, only Pfizer, Roche and Bayer are FERA companies. This Department has not granted or recommended any loan licence to these companies. The others being non-FERA companies, are not prohibited from lean licensing.

As Government's approval is not required for marketing arrangements, details of such arrangements are not available.

Production of drug by Glaxo and Hoechst

2836. SHRI SYED RAHMAT ALI: Will the Minister of INDUSTRY be pleased to refer to the answer to Unstarred Question 973 given in the Rajya Sabha on the 25th November, 1985 and state:

(a) whether it is a fact that Glaxo and Hoechst have indicated the total licensed capacity of tablets, capsules liquid and ointments in their balance sheets;

(b) whether it is a fact that these companies have indicated the production figures of each formulation of the pertaining year;

(c) if so, what are the basis on which these figures have been taken;

(d) what is the system adopted by Government to check under or over-production of formulations;

(e) whether it is also a fact that Industrial Licences cover the permitted capacity of formulations along with the drug; and

(f) if so, the number of Industrial Licences issued to each of these two companies along with name of bulk drug and formulations as well as the capacity permitted for each drug during the last three years?

THE MINISTER OF STATE IN THE DEPARTMENT OF CHEMICALS AND PETROCHEMICALS (SHRI R. K. JAICHANDRA SINGH): (a) Yes, Sir.

(b) Total production of various dosage forms is also shown in the balance sheet.

(c) No details are available with the Government.

(d) Production of formulations is not monitored. As and when applications are received for industrial approvals, Government verify compliance with ratio parameters laid down under 1978 Drug Policy.

(e) and (f) Industrial approvals generally do not specify the drug capacity for

each and every formulation and pack. Details of Industrial Approvals issued from time to time are published in the monthly News Letter at Indian Investment Centre, copies of which are available in the Parliament Library.

Production of bulk drugs

2837. SHRIMATI MAIMOONA SULTAN: Will the Minister of INDUSTRY be pleased to state:

(a) names of bulk drugs being produced by Warner Hindustan, Bayer, Hoechst, Pfizer, Abbot, Wockhardt, Glaxo Faidcal Corporation, Roche, Dolphine, Lyka, E-Merck, Cynamide, Searle, Wyeth and Geofary Manner along with stage of manufacture of each drug by each company as well as production during the last three years, year-wise;

(b) what was the ratio of each company of the ex-factory value of production of bulk drugs in relation to the ex-factory value of production of formulations during the last three years, year-wise; and

(c) what was the ex-factory value per kg. of bulk drug taken by each company for working the total ex-factory value along with notified price and selling price of each company of each drug?

THE MINISTER OF STATE IN THE DEPARTMENT OF CHEMICALS AND PETROCHEMICALS (SHRI R. K. JAICHANDRA SINGH): (a) To the extent information is available details are given in the attached Statement-I.

(b) and (c) To the extent information available, details of ratio of value of production of bulk drugs to value of production of formulations are given in the attached Statement-II. Details of notified prices of bulk drugs are published in the Official Gazette notification from time to time, copies of which are available in the Parliament Library. The prices fixed under DPCO 1979 are the maximum selling prices and the manufacturers are free to sell at prices lower than the prices so fixed. No instances of manufacturers selling at prices above valid in law have come to the notice of the Government.

Statement –I

Production of M/S. Wyeth labs

Sl. No.	A/C Name of the drug	A/C Unit	Production		
			1982-83	1983-84	1984-85
1	2	3	4	5	6
1	Hydrocortisone Acetate	Kg.	59.96	108.54	138.28
2	Testosterone	Kg.	12.01	35.00	25.00
3	Testosterone Enanthate	Kg.	77.39	125.12	133.01
4	17 Alpha Hydroxy Progesterene Capreate	Kg.	615.40	1547.18	1110.94
5	Ethopeptazine Citrate	Kg.	1082.10	3285.00	1959.10
6	Hydrocortisone	Kg.	105.91	124.36	52.40
7	Methyltestosterone	Kg.	..	21.50	19.40
8	17 Alpha Acetoxy Progesterone (Tech.)	Kg.	289.00	490.80	714.95
9	Progesterone	Kg.	1.40	19.90	76.60